510(k) SUMMARY
AS REQUIRED BY SECTION 807.92(C)

JUL 17 2012

The Assigned 510(k) number is: k112101

Date of Summary: July 13, 2012

Common Name: **hCG (Human Chorionic Gonadotropin)** Pregnancy Serum/Urine Combo Test

Regulatory Information:

1. Regulation section: 21 CFR part 862.1155, Human Chorionic Gonadotropin test system
2. Classification: Class II
3. Product Code: JHI, radioimmunoassay, human chorionic gonadotropin
4. Panel: Clinical Chemistry 75

Applicant and Initial Importer:

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Contact Persons:

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Identification / Product Name:

Fastep™ hCG Pregnancy Serum/Urine Test

510(k) SUMMARY (Cont.)

Description:
The Fastep™ hCG Pregnancy Serum/Urine Test are distributed in Cassette format. Each test reagent strip contains mouse monoclonal anti-α-hCG antibody coated membrane and a dried chemical pad containing mouse monoclonal anti-β-hCG anybody colloidal gold conjugate. The control antibodies are goat anti-mouse IgG.

Intended Use:
The Polymed Therapeutics' Fastep™ hCG Pregnancy Serum/Urine Test is rapid chromatographic immunoassays for the visual, qualitative detection of human chorionic gonadotropin (hCG) in serum or urine specimen to aid in the early detection of pregnancy. For Professional Use Only.

The test kits are for health care professionals use including professionals at physician's office labs (POLs) or point-of-care site (POC).

Predicate Kit:
Teco Diagnostics One-Step Urine/Serum Combo Pregnancy Card Test is used as predicate device for Polymed Therapeutics' Fastep™ hCG Pregnancy Serum/Urine Test to compare their performance of required studies. The clinical serum specimens used for accuracy study were quantitatively confirmed by Abbott Architect i2000 instrument.

510(k) numbers for predicate devices are:

Abbott Architect i2000 instrument	k093318
Teco Diagnostics One-Step Urine/Serum Combo Pregnancy Test	k964461

Performance:
The product performance characteristics of Polymed Therapeutics' Fastep™ hCG Pregnancy Serum/Urine Test was evaluated in the blind-labeled spiked control studies and blind-labeled clinical specimen correlation study (including POLs site study). The results of these studies demonstrate Polymed Therapeutics' Fastep™ hCG Pregnancy Serum/Urine Test to be substantially equivalent to the performance characteristics of Teco's One Step Pregnancy Urine/Serum Test. Correlation studies, using 145 clinical specimen sets, produced a minimum of 98.3% accuracy.

Accuracy Results:

A. Urine sample

		Teco One-Step Combo Card Test		
		+	-	Total
Fastep™ Cassette Panel	+	59	0	59
	-	0	86	86
	Total	59	86	145

Sensitivity = (59 / (59+0)) x100 = 100.0%; Specificity = (86 / (86+0)) x 100 = 100.0%

B. Serum sample
51 positive and 86 negative quantitative confirmed serum specimens were evaluated. The results of the accuracy finding calculated against predicate device are summarized and presented in the form of a 2x2 table (shown below):

		Teco One-Step Combo Card Test		
		+	-	Total
Fastep™ Cassette Panel	+	58	0	58
	-	1	86	87
	Total	59	86	145

Sensitivity = 58/(58+1)) x100 = 98.3%; Specificity = (86/(86+0)) x 100 = 100.0%

Sensitivity and Cross-reactivity

The Fastep™ hCG Pregnancy Serum/Urine Test detects serum or urinary hCG at a concentration of 20mIU/ml or greater. The test has been standardized to the WHO Fourth International Standard 75/589.

Cross-reactivity (Specificity) evaluated at negative (0 mIU/ml) and positive (20 mIU/ml) hCG specimens showed no cross-reaction:

Compounds (level)	% Non-cross-reactivity
hCG (20 mIU/ml)	100%
hLH (300 mIU/ml)	1,500%
hFSH (1,000 mIU/ml)	5,000%
hTSH (1,000 µIU/mL)	5%

Precision (POL sites)

Lab spiked hCG urine and serum controls were used to evaluate the precision performance of Fastep™ hCG Pregnancy Serum/Urine Cassette and Dipstick Tests. 3 lots devices were evaluated at 3 Point-of-care sites by 9 operators.

A. Serum controls

Levels (mIU/ml)	No. of Negative	No. of Positive	% Negative	% Positive
0	**225**	**0**	**100%**	**0%**
10	**225**	**0**	**100%**	**0%**
15	**225**	**0**	**100%**	**0%**
20	**7**	**218**	**3.1%**	**96.9%**
40	**0**	**225**	**0%**	**100%**
100	**0**	**225**	**0%**	**100%**

B. Urine controls

Levels (mIU/ml)	No. of Negative	No. of Positive	% Negative	% Positive
0	**225**	**0**	**100%**	**0%**
10	**225**	**0**	**100%**	**0%**

15	**225**	**0**	**100%**	**0%**
20	**7**	**218**	**3.1%**	**96.9%**
40	**0**	**225**	**0%**	**100%**
100	**0**	**225**	**0%**	**100%**

Interference

The performance of Fastep™ hCG Serum/Urine Pregnancy test at negative and cutoff points are not affected when the pH range of urine specimens is at 3.0 to 8.5 and the specific gravity range of urine specimens is at 1.00 to 1.03.

The following substances were added to hCG free and 20mIU/ml hCG spiked serum and urine samples. None of the substances at the concentration tested interfered with the assay.

Substances	Con. in Serum	Con. in Urine
Acetaminophen	20 mg/dl	20 mg/dl
Acetylsalicylic Acid	20 mg/dl	20 mg/dl
Albumin	2000 mg/dl	2000 mg/dl
Ascorbic Acid	20 mg/dl	20 mg/dl
Atropine	20 mg/dl	20 mg/dl
Bilirubin	40 mg/dl	2 mg/dl
Caffeine	20 mg/dl	20 mg/dl
EDTA	80 mg/dl	80 mg/dl
Ethanol	1%	1%
Gentesic Acid	20 mg/dl	20 mg/dl
Glucose	2 g/dl	2 g/dl
Hemoglobin	125 mg/dl	1 mg/dl
Methanol	1 %	1 %
Salicylic Acid	20 mg/dl	20mg/dl
Triglyceride	1200 mg/dl	N/A

*: β-core hCG level up to 8.53 pmol/L does not interfere with the assay.

Conclusion:

Of these specimen sets tested in serum and urine device, results of Accuracy, POL site study demonstrate the substantial equivalency between Polymed Therapeutics' Fastep™ hCG Pregnancy Serum/Urine Test and the Teco One- Step Pregnancy Urine/Serum Test panel. It is also demonstrated that Polymed Therapeutics' Fastep™ hCG Pregnancy Serum/Urine Test is safe and effective in detecting human chorionic gonadotropin (hCG) in serum or urine sample to aid in the early determination of pregnancy.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

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Silver Spring, MD 20993

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JUL 17 2012

Re: k112101
Trade Name: Fastep™ hCG Pregnancy Serum/Urine Cassette Tests
Regulation Number: 21 CFR §862.1155
Regulation Name: Human chorionic gonadotropin (hcg) test system
Regulatory Class: Class II
Product Codes: JHI
Dated: June 20, 2012
Received: July 9, 2012

Dear Feng-Yu Lee:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance...

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm

Sincerely yours,

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): K112101

Device Name: **Polymed Therapeutics' Fastep™ hCG Pregnancy Serum/Urine Test**

Indications for Use:

The Polymed Therapeutics' Fastep™ hCG Pregnancy Serum/Urine Test is a rapid chromatographic immunoassays for the visual, qualitative detection of human chorionic gonadotropin (hCG) in serum or urine specimen to aid in the early detection of pregnancy. For Professional Use Only.

The test kits are for health care professionals use including professionals at physician's office labs (POLs) and Point-of-Care site (POC).

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety
510(k) K112101